DEC 2 8 2006

Atty Docket No. 02307O-139300US

PTO FAX NO.: 1-571-273-8300

ATTENTION:

Examiner Alana M. Harris

Group Art Unit 1643

OFFICIAL COMMUNICATION FOR THE PERSONAL ATTENTION OF

EXAMINER Alana M. Harris

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that the following documents in re Application of Joe W. Gray et al., Application No. 10/616,403, filed July 8, 2003 for BREAST CANCER GENES are being facsimile transmitted to the Patent and Trademark Office on the date shown below.

Documents Attached

- 1. PETITION TO WITHDRAW HOLDING OF ABANDONMENT
- COPY of date-stamped, return postcard
- 3. COPY of response filed December 1, 2006 (Transmittal Form, Petition for five month Extension of Time, and AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT).

Number of pages being transmitted, including this page: 11

Dated: December 28, 2006

Malinda C. Dagit

PLEASE CONFIRM RECEIPT OF THIS PAPER BY RETURN FACSIMILE AT (415) 576-0300

TOWNSEND and TOWNSEND and CREW LLP Two Embarcadero Center, Eighth Floor San Francisco, CA 94111-3834 Telephone: 415-576-0200

Fax: 415-576-0300

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DEC 2 8 2086

 PATENT

Attorney Docket No.: 02307O-139300U Client Ref. No.: 2003-534-1

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Joe W. Gray et al.

Application No.: 10/616,403

Filed: July 8, 2003

For: BREAST CANCER GENES

Customer No.: 20350

Confirmation No. 9224

Examiner:

Alana Harris

Group Art Unit:

1643

PETITION TO WITHDRAW HOLDING

OF ABANDONMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants are in receipt of the Notice of Abandonment mailed December 15, 2006, indicating the above-identified application has been abandoned for failure to respond to the Office Communication mailed June 1, 2006. Applicants respectfully request withdrawal of the holding of abandonment because an Amendment and Response to Restriction Requirement with a fee authorization for a five month extension of time was filed on December 1, 2006. The holding of abandonment is therefore incorrect. Enclosed herewith are:

1. A copy of the date-stamped, return postcard sent with the Amendment and Response to Restriction Requirement and Petition Extending Time and accompanying documents, mailed for filing via First Class Mail on December 1, 2006, showing receipt by the Patent and Trademark Office on December 18, 2006;

Appl. No. 10/616,403 Petition to Withdraw Holding of Abandonment dated December 28, 2006 **PATENT**

2. A copy of the Amendment and Response to the Restriction Requirement with the Petition Extending Time with a fee authorization for five months, and the transmittal mailed for filing on December 1, 2006.

Applicants received an Office Communication setting forth a restriction requirement that was mailed from the Patent and Trademark Office on June 1, 2006. On December 1, 2006, Applicants filed an appropriate response with an accompanying Petition Extending Time and fee authorization for five months. The Transmittal sheet for the response has a signed and dated first class certificate of mailing, showing that it was mailed on December 1, 2006. A return receipt postcard was also filed with the response. The postcard has a date stamp of December 18, 2006, showing receipt of the documents by the Patent and Trademark Office. The fee for the extension of time authorized in the Petition Extending Time was also charged on December 18, 2006. Applicants therefore responded to the Office Communication in an appropriate and timely manner.

In view of the foregoing, Applicants respectfully request withdrawal of the holding of abandonment. If a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

Jean M. Lockyer Reg. No. 44,879

TOWNSEND and TOWNSEND and CREW LLP

Two Embarcadero Center, Eighth Floor San Francisco, California 94111-3834

Tel: 415-576-0200 Fax: 415-576-0300

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TO THE U.S. PATENT AND TRADEMARK OFFICE

	pt of the following document(s) and return this card to us:	
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Please stamp the date	of receipt of the following document(s) and return this card to us.				
INVENTOR(S):	loe W. Grav et al.				
RE:	PATENT APPLN. FILED 07/08/03 FOR "BREAST CANCER GENES"				
TITLE OF DOCUMENT(S):	Amendment and Response to Restriction Requirement: Petition Extending Time PTO/SB/22 for 5 mos. @\$1080 (orig.+1); Transmittal Form PTO/SB/21.				
Application No.	10/616,403				
File No.	02307O-1393-00U-				
Date Due	1 Dec. 2006				
Date Mailed	1 Dec. 2000				
Attorney/Secretary	JML/mcd DEC 18 7006				

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			PTO/SB/21 (07-06)			
TRANSMITTAL FORM		Application Number 10/616,403				
		Filing Date	July 8, 2003			
		First Named Inventor	Gray, Joe W.			
		Art Unit	1643			
(to be used for all correspondence after initial filing)		Examiner Name	Alana M. Harris			
Total Number of Pages in Ti	his Submission 8	Attorney Docket Number	02307O-139300US			
	EN	CLOSURES (Check all that				
Fee Transmittal For	m 📙	Drawing(s)	After Allowance Communication to TC			
Fee Attache	ed 🔲	Licensing-related Papers	Appeal Communication to Board of Appeals and Interferences			
Amendment/Reply- and Response to F		Petition	Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)			
Requirement" After Final		Petition to Convert to a Provisional Application	Proprietary Information			
Affidavits/de	eclaration(s)	Power of Attorney, Revocation Change of Correspondence Address	Status Letter			
Extension of Time F per PTO/SB/22 (in		Terminal Disclaimer	Other Enclosure(s) (please identify below):			
Express Abandonm	ent Request	Request for Refund	Return Postcard			
Information Disclosu	ure Statement	CD, Number of CD(s)				
						
	iodh: Rem	Landscape Table on CD	uthorized to charge any additional fees to Deposit			
Certified Copy of Pri Document(s)	ionty Rem	Account 20-1430.	buildized to charge any additional fees to Deposit			
Reply to Missing Parts/ Incomplete Application Reply to Missing Parts under 37 CFR 1.52 or 1.53						
·	SIGNATURE	OF APPLICANT, ATTORN	EY, OR AGENT			
Firm Name Towns	send and Townsend ar		•			
Signature	MM	W				
Printed name Jean	M. Lockyer, Ph.D.)					
Date Decem	nde: 1, 2006	Reg. No.	44,879			
CERTIFICATE OF TRANSMISSION/MAILING						
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.						
Signature	Signature Mulwala Cashs					
Typed or printed name	Typed or printed name Malinda C. Dagit Date / Dec., 2006					

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DEC 2 8 2066

PTO/SB/22 (07-06)

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)			Docket Number (Optional) 02307O-139300US			
FY 2006 (Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)						
Applic	ation Number 10/616,403	Filed July 8, 2003				
For E	BREAST CANCER GENES					
Art Un	uit 1643		Examiner Alana M. Ha	arris		
This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.						
The re	equested extension and fee are as follows (check tin	ne period desired	and enter the appropriate	e fee below):		
		<u>Fee</u>	Small Entity Fee			
	One month (37 CFR 1.17(a)(1))	\$120	\$60	\$		
	Two months (37 CFR 1.17(a)(2))	\$450	\$225	\$		
	Three months (37 CFR 1.17(a)(3))	\$1020	\$510	\$		
	Four months (37 CFR 1.17(a)(4))	\$1590	\$795	\$		
	Five months (37 CFR 1.17(a)(5))	\$2160	\$1080	\$_1080		
Applicant claims small entity status. See 37 CFR 1.27.						
A check in the amount of the fee is enclosed.						
	Payment by credit card. Form PTO-2038 is attached	ed.				
\boxtimes	The Director has already been authorized to charge	e fees in this appli	cation to a Deposit Accou	unt.		
The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to						
Deposit Account Number 20-1430 . I have enclosed a duplicate copy of this sheet. WARNING: Information on this form may become public. Credit card information should not be included on this form.						
	Provide credit card information and authorization on PTC	D-203 8.		•		
	n the applicant/inventor.					
ıan						
	assignee of record of the entire in Statement under 37 CFR 3.73	iterest. See 37 Ch 3(b) is enclosed (F	orm PTO/SB/96).			
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96). attorney or agent of record. Registration Number 44,879						
attorney or agent under 37 CFR 1.34.						
Registration number If acting under 37 CFB-1:34						
December 1, 2006						
Signature Date						
Jear M. Lockyer, Ph.D., Reg. No. 44,879			415-576-0200			
Typed or printed name Telephone Number						
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.						
	Total of forms are sub-	mitted				

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

PATENT

Attorney Docket No.: 02307O-139300US

Client Ref. No.: 2003-534

Mail Stop Amendment Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Joe W. Gray et al.

Application No.: 10/616,403

Filed: July 8, 2003

For: BREAST CANCER GENES

Customer No.: 20350

Confirmation No. 9224

Examiner:

Alana Harris

Group Art Unit:

1643

AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed June 1, 2006, please enter the following amendments and remarks. Enclosed herewith is a petition with fee authorization for a fivemonth extension of time.

Amendments to the Claims are reflected in the listing of claims that begins on page 2 of this paper.

Remarks begin on page 5 of this paper.

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Appl. No. 10/616,403 Amdt. dated December 1, 2006 Reply to Office Action of June 1, 2006 PATENT

Amendments to the Claims:

This listing of claims will replace all prior listings of claims in the application:

Listing of Claims:

1. (currently amended) A method of detecting a breast cancer cell in a biological sample from a patient, the method comprising

contacting the sample with a polynucleotide that selectively hybridizes to a nucleic acid sequence encoding a polypeptide having an amino acid sequence of SEQ ID NO:2, SEQ ID NO:4, or SEQ ID NO:6; and

detecting an increase in the level of the nucleic acid sequence, relative to normal, thereby detecting the presence of a breast cancer in the patient.

- 2. (original) The method of claim 1, wherein the detecting step comprises detecting an mRNA that encodes the polypeptide.
- 3. (original) The method of claim 2, wherein the mRNA is detected using an amplification reaction.
- 4. (original) The method of claim 1, wherein the detecting step comprises detecting an increase in copy number of the nucleic acid that encodes the polypeptide.
- 5. (original) The method of claim 1, wherein the patient is undergoing a therapeutic regimen to treat breast cancer.
- 6. (original) The method of claim 1, wherein the patient is suspected of having breast cancer.
- 7. (original) A method of detecting a breast cancer cell in a biological sample from a patient, the method comprising

Appl. No. 10/616,403 Amdt. dated December 1, 2006 Reply to Office Action of June 1, 2006 PATENT

detecting an increase in the level of a polypeptide having an amino acid sequence of SEQ ID NO:2, SEQ ID NO:4, or SEQ ID NO:6, relative to normal, thereby detecting the presence of a breast cancer in the patient.

- 8. (original) The method of claim 7, wherein the step of detecting an increase in the level of the polypeptide comprises performing an immunoassay.
- 9. (original) A method of monitoring the efficacy of a therapeutic treatment of cancer, the method comprising the steps of:
- (i) providing a biological sample from a patient undergoing the therapeutic treatment; and
- (ii) detecting the level of: a polypeptide having an amino acid sequence of SEQ ID NO:2, SEQ ID NO:4, or SEQ ID NO:6, or of a nucleic acid that encodes the polypeptide, in the biological sample compared to a level in a biological sample from the patient prior to, or earlier in, the therapeutic treatment, thereby monitoring the efficacy of the therapy.
- 10. (original) A method for identifying a compound that modulates a breast cancer-associated polypeptide, the method comprising the steps of:
- (i) contacting the compound with a polypeptide of SEQ ID NO:2, SEQ ID NO:4, or SEQ ID NO:6; and
 - (ii) determining the functional effect of the compound upon the polypeptide.
- 11. (original) A method of inhibiting proliferation of a breast cancer cell that overexpresses a polypeptide having an amino acid sequence of SEQ ID NO:2, SEQ ID NO:4, or SEQ ID NO:6, the method comprising the step of contacting the cancer cell with a therapeutically effective amount of an inhibitor of the polypeptide.
- 12. (original) The method of claim 11, wherein the gene that encodes the polypeptide is increased in copy number in the breast cancer cell.

Appl. No. 10/616,403 Amdt. dated December 1, 2006 Reply to Office Action of June 1, 2006 PATENT

- 13. (original) The method of claim 11, wherein the inhibitor is an antibody,
- 14. (original) The method of claim 11, wherein the inhibitor is a small molecule.
- 15. (new) The method of claim 1, wherein the biological sample is breast tissue.

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Appl. No. 10/616,403 Amdt. dated December 1, 2006 Reply to Office Action of June 1, 2006

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REMARKS

With entry of the instant amendment, claim 1 has been amended and new claim 15 has been added. New claim 15 recites that the biological sample is breast tissue. This amendment adds no new matter and is supported throughout the application as filed, e.g., at paragraph 3.

In response to the restriction requirement, Applicants elect Group I, claims 1-6 and 15, relating to a method of detecting a breast cancer cell in a biological sample by detecting a nucleic acid sequence encoding a polypeptide having the sequence set forth in SEQ ID NO:2.

The foregoing election, insofar as it relates to the restriction among different method claims, is made with traverse. According to the MPEP, where claims can be examined together without undue burden, the Examiner must examine the claims on the merits even though they are directed to independent and distinct inventions. (See, the MPEP at 803.01.) In establishing that an "undue burden" would exist for co-examination of claims, the Examiner must show that examination of the claims would involve substantially different prior art searches, making the co-examination burdensome. Here, a search of the subject matter of elected Group I would likely encompass the subject matter of Groups IV, VII, X, and XIII. Accordingly, these groups could be searched together without undue burden. Applicants therefore respectfully request reconsideration of the restriction requirement.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

Jean M. Lockye Reg. No. 44,879

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